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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/576,908	12/18/2006	Amar Lulla	PAC/23361 US (4137-00700)	9899
30652 7590 04/30/2010 CONLEY ROSE, P.C. 5601 GRANITE PARKWAY, SUITE 750 PLANO, TX 75024			EXAMINER PURDY, KYLE A	
			ART UNIT 1611	PAPER NUMBER
			MAIL DATE 04/30/2010	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/576,908	Applicant(s) LULLA ET AL.	
	Examiner Kyle Purdy	Art Unit 1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 1/6/2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7 and 10-20 is/are pending in the application.
- 4a) Of the above claim(s) 18-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7 and 10-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Application

1. The Examiner acknowledges receipt of the amendments filed on 1/06/2010 wherein claim 1 has been amended.
2. Claims 1-7 and 10-16 are presented for examination on the merits. The following rejections are made.

Response to Applicants' Arguments

3. Applicants arguments filed 1/06/2010 regarding the rejection of claims 1-4, 6, 7 and 11-16 made by the Examiner under 35 USC 102(b) over Wain et al. (WO 00/45795) have been fully considered and they are found persuasive. This rejection has been overcome by amendment to the claim.
4. Applicants arguments filed 1/06/2010 regarding the rejection of claims 1-7 and 10-16 made by the Examiner under 35 USC 103(a) over Wain in view of Foldvari (PSST, 2000) have been fully considered but they are not found persuasive.
5. The rejection of claims 1-7 and 10-16 made by the examiner under 35 USC 103(a) is **MAINTAINED** for the reasons of record in the office action mailed on 8/11/2009.
6. In regards to the 103(a) rejection, Applicant asserts the following:
 - A) Wain does not disclose the feature of the composition comprising about 70% ethanol.
7. In response to A, the Examiner disagrees. Applicant is directed to claims 3 and 18 of Wain. Claim 3 states that the composition may comprise up to 90% of the vehicle, where claim 18 defines the vehicle as including absolute alcohol (i.e. ethanol). Therefore, one would have been motivated to formulate a composition comprising up to 90% ethanol.

Maintained Rejections, of Record
Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 1-7 and 10-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wain et al. (WO 00/45795; of record, see IDS) in view of Foldvari (PSTT, 2000, 3(12), 417-425).

10. Wain is relied upon for disclosure described in the rejection of claims 1-4, 6-7 and 11-16 under 35 U.S.C. 102(b).

11. Wain fails to teach transdermal permeation enhancers as being selected from menthol, dimethylisobornide, glycerylmonooleate and myristyl lactate.

12. Foldvari is a review article drawn to non-invasive administration of drugs through the skin. It is taught that menthol (terpene) is a useful penetration enhancer which acts by disrupting intercellular lipid orders (see instant claim 10). Moreover, addition of menthol to skin increases net electrical conductivity which indicates the opening of polar pathways in the stratum corneum and allows for simplifying the passage of active agents (see Table 1, page 420).

13. Thus, one ordinarily skilled in the art, at the invention was made would be motivated to combine the teachings of Wain and Foldvari with a reasonable expectation for success in arriving at a transdermal spray formulation comprising a pharmaceutically active agent, a VP-VA copolymer, a non-aqueous vehicle, a penetration enhancer, and a anti-nucleating agent at the

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required weight percentages. Wain teaches a composition which comprises an active agent (estradiol), an anti-nucleating agent (PVP-k 30), a film forming polymer (PVP-VA), penetration enhancer (PEG) and non-aqueous solvents acetone (acetone, ethanol and methylene chloride). Although Wain includes penetration enhancers in their composition, Wain fails to specifically disclose using menthol as such. Foldvari et al. is a review article drawn to penetration enhancers and their use to improve transdermal delivery of pharmacologically active agents. It is specifically taught that menthol is useful as a penetration enhancer. As Wain motivates using a penetration enhancer in the composition, it follows that employing any penetration enhancer would be useful so long as it fulfills the role of performing its function. If one arrived at menthol out of the many potential enhancers and the product was successful, such a result would not be due to innovation but rather due to ordinary skill and common sense. Therefore, the invention as a whole is *prima facie* obvious to one ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in absence of evidence to the contrary.

Conclusion

14. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

15. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

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CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kyle A. Purdy whose telephone number is 571-270-3504. The examiner can normally be reached from 9AM to 5PM.

17. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau, can be reached on 571-272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

18. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

*/Kyle Purdy/
Examiner, Art Unit 1611
April 21, 2010*

*/David J Blanchard/
Primary Examiner, Art Unit 1643*